JUN 2 7 2000

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K#000707

1. Submitter's Identification:

Leica Microscopy Systems Ltd.
Business Unit SM
3362 Walden Avenue
Depew, NY 14043

Contact:

Mr. Frank Edwards
North American Sales & Marketing Manager

Date Summary Prepared:
February, 2000

2. Name of the Device:

Leica Colposcopes, MS-5 and MZ-6

3. Predicate Device Information:

Identification of Legally Marketed Device Which We Claim Substantial Equivalence (Predicate Device):

1. Leisegang Video Colposcope (LMZ), K#940094, K#981958, Leisegang Medical, Inc., Boca Raton, Florida

2. Wallach Colposcope (Tristar), K#871681/2/3, Wallach Surgical Devices, Inc., Orange, Connecticut

4. Device Description:

a. Executive Summary:

The Leica Colposcopes, MS-5 and MZ-6 are intended for magnified viewing of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy.

Tissue is magnified and viewed directly via binocular microscopes with the options for recording and transmitting images through video and digital imaging. These image systems provide recorded documentation for the physician or nurse practitioner to review for diagnostic purposes. The Leica Colposcopes have a non-patient contact of up to 300 mm.

b. Device Description:

The Leica Colposcopes, MS-5 and MZ-6 are a non-patient contacting Stereomicroscope with a zoom factor 6:1, working distances of between 250-300 mm, and a green filtered light source mounted on a floor stand.

5. Intended Use:

The Leica Colposcopes, MS-5 and MZ-6 are intended for magnified viewing of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy.

6. Comparison to Predicate Devices:

The Leica (subject device), Leisegang and Wallach Colposcopes are all intended to permit direct viewing and imaging of the tissues of the vagina, cervix and external genitalia to diagnose abnormalities and select areas for biopsy. The Leica and Leisegang Colposcopes rely on a similar style of zoom optical systems and objectives that provide the necessary working distances required for patient observation. The Leica and Leisegang Colposcopes also offer photo and video capabilities that are integrated into the optical path of the microscope. These imaging systems provide the physician/nurse practitioner with a means to record pictures of the tissues for review over time. All three devices are offered with similar floor and table mounting stands.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The following Standards were met:

- IEC 60601-1
- IEC 60601-1-2
- Cold Light Source Certification

8. Discussion of Clinical Tests Performed:

Not Applicable

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9. Conclusions:

The Leica Colposcopes have the same intended use and similar technological characteristics as the Leisegang Colposcope and the Wallach Colposcope. Moreover, the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the Leica Colposcope is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2000

Leica Microscopy Systems Ltd.
c/o Ms. Susan D. Goldstein-Falk
Official Correspondent for
Leica Microscopy Systems, Ltd.
MDI Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K000707
Leica Colposcopes, Models MS-5 and MZ-6
Dated: June 8, 2000
Received: June 12, 2000
Regulatory Class: II
21 CFR §884.1630/Procode: 85 HEX

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

Exhibit B

510(k) Number (if known): K#000707

Device Name: Leica Colposcopes, MS-5 and MZ-6

Indications For Use:

The Leica Colposcopes MS-5 and MZ-6 are intended for magnified viewing of the vagina, cervix and external genitalia in order to diagnose abnormalities and select areas for biopsy.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000707